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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Judith Fitzpatrick, Regina B. Lenda, and Christopher L. Jones

Serial No.: 09/526,582

Art Unit: Not Yet Assigned

Filed: March 16, 2000

Examiner: Not Yet Assigned

For: *METHOD AND DEVICE FOR DETECTION OF APO A, APO B AND THE  
RATIO THEREOF IN SALIVA*Assistant Commissioner for Patents  
Washington, D.C. 20231**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including ten (10) pages of Form PTO-1449 and a copy of each document cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 01-2507.

**U.S. Patents**

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
5,451,504	09-19-1995	Fitzpatrick, et al.	435/7.2
5,500,375	03-19-1996	Lee-Own, et al.	436/514
5,710,009	01-20-1998	Fitzpatrick, et al.	435/7.9

**Foreign Patent Documents**

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
WO 93/18067	09-16-1993	Abbott Laboratories	PCT
WO 96/00903	01-11-1996	Oklahoma Medical Research Foundation	PCT

WO 98/06827

02-19-1998

Serex, Inc.

PCT

### Publications

"Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents," *Pediatrics* 89:525-584 (1992).

"Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High-Blood Cholesterol in Adults," *Arch. Intern. Med.* 148:36-69 (1988).

"Report of the Working Group on Atherosclerosis of the National Heart and Lung and Blood Institute," 2 (Washington, D.C.: Government Printing Office, 1981) DHEW Publication No. (NIH) 82-2035).

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U.S.S.N.: 09/526,582  
Filed: March 16, 2000  
INFORMATION DISCLOSURE STATEMENT

### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

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Patrea L. Pabst  
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Dated: June 26, 2000

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Filed: March 16, 2000  
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Julie A. Tennyson

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	09/526,582
		Filing Date	March 16, 2000
		First Named Inventor	Judith Fitzpatrick
		Group Art Unit	
		Examiner Name	
Sheet 1 of 10	Attorney Docket Number	SRX 110	

#### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
		5,451,504		Fitzpatrick, et al.	09-19-1995	
		5,500,375		Lee-Own, et al.	03-19-1996	
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#### FOREIGN PATENT DOCUMENTS

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		WO	93/18067		Abbott Laboratories	09-16-1993		
		WO	96/00903		Oklahoma Medical Research Foundation	01-11-1996		
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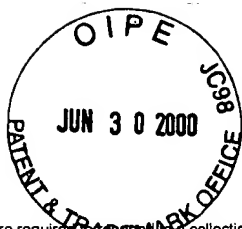
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		Application Number	09/526,582
		Filing Date	March 16, 2000
		First Named Inventor	Judith Fitzpatrick
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Sheet 2 of 10	Attorney Docket Number	SRX 110	

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		"Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents," <i>Pediatrics</i> 89:525-584 (1992).	
		"Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," <i>Arch. Intern. Med.</i> 148:36-69 (1988).	
		"Report of the Working Group on Atherosclerosis of the National Heart and Lung and Blood Institute," 2 (Washington, D.C.: Government Printing Office, 1981) DHEW Publication No. (NIH) 82-2035).	
		"The Lipid Research Clinics Coronary Primary Prevention Trial Results: II," <i>JAMA</i> , 251:365-374 (1984).	
	✓	ALAPOVIC, "David Rubinstein Memorial Lecture: The Biochemical and Clinical Significance of the Interrelationship Between Very Low Density and High Density Lipoproteins," <i>Can. J. Biochem.</i> 59:565-579 (1981).	
		ALAPOVIC, et al., "Characterization of Potentially Atherogenic Triglyceride-rich Lipoprotein Particles," <i>Klin Wochenschr.</i> 68:38-42 (1990).	
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	✓	ALAPOVIC, et al., "Isolation and characterization of an apoA-II-containing lipoprotein (LP-A-II:B complex) from plasma very low density lipoproteins of patients with Tangier disease and type V hyperlipoproteinemia," <i>J. Lipid Res.</i> 32(1):9-19 (1991).	
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		ATMEH, et al., "Subpopulations of Apolipoprotein A-I in Human High-Density Lipoproteins, Their Metabolic Properties and Response to Drug Therapy," <i>Biochim. Biophys. Acta.</i> 751:175-188 (1983).	
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		BLANKENHORN, et al., "Prediction of Angiographic Change in Native Human Coronary Arteries and Aortocoronary Bypass Grafts," <i>Circulation</i> 81(2):479-476 (1990).	
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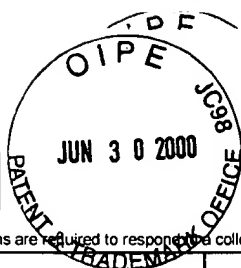
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/526,582
Filing Date	March 16, 2000
First Named Inventor	Judith Fitzpatrick
Group Art Unit	
Examiner Name	
Attorney Docket Number	SRX 110

Sheet 4 of 10

### OTHER ART – NON PATENT LITERATURE DOCUMENTS

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		CURRY, et al., "Quantitative Determination of Human Apolipoprotein C-III by Electroimmunoassay," <i>Biochim. Biophys. Acta.</i> 617:503-513 (1980).	
		CWIRLA, et al., "Peptides on phage: A vast library of peptides for identifying ligands," <i>Proc. Natl. Acad. Sci. USA</i> 87:6378-6382 (1990).	
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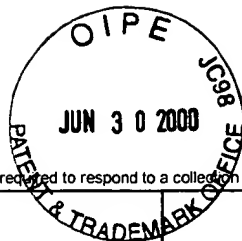
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		GOHLKE, "Influence of the LDS-/HDL-Cholesterol Ratio on Progression and Regression of Atherosclerotic Lesions. A Review of Controlled Angiographic Intervention Trials," <i>Wien Klin. Wochenschr.</i> 104(11):309-313 (1992).	
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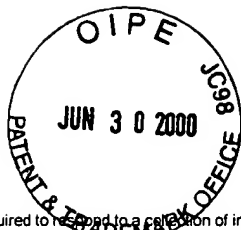
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		Filing Date	March 16, 2000
		First Named Inventor	Judith Fitzpatrick
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		Examiner Name	
		Attorney Docket Number	SRX 110
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		KWITEROVICH, et al., "Comparison of the Plasma Levels of Apolipoprotein B and A-1, and Other Risk Factors in Men and Women with Premature Coronary Artery Disease," <i>Am. J. Cardiol.</i> 69:1015-1021 (1992).	
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		MARCEL, et al., "Expression of human apolipoprotein A-I epitopes in high density lipoproteins and in serum," <i>J. Lipid Res.</i> 28(7):768-77 (1987).	
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		ORTOLA, et al., "Biological Variation Data Applied to the Selection of Serum Lipid Ratios used as Risk Markers of Coronary heart Disease," <i>Clin. Chem.</i> 38(1):56-59 (1992).	
		OSBORNE & BREWER, "The plasma lipoproteins," <i>Adv. Protein Chem.</i> 31:253-337 (1977).	

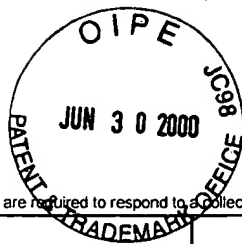
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		PARHAM, "Handbook of Experimental Immunology, Vol. 1: Immunochemistry," (Weir, D.M., Editor), Blackwell Scientific Publications: Oxford, 1986.	
		PARMEY, et al., "Filamentous Fusion Phage Cloning Vectors for the Study of Epitopes and Design of Vaccines," <i>Adv. Exp. Med. Biol.</i> 251:215-218 (1989).	
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		RABINOWITZ & SHANNON, "Lipid changes in human male parotid saliva by stimulation," <i>Arch. Oral Biol.</i> 20(7):403-6 (1975).	
		RIFAI, et al., "Introduction," <i>Atherosclerosis</i> 108(Suppl):S1-S2 (1994).	
		SAVAGE, et al., "Avidin-Biotin Chemistry: A Handbook," Pierce Chemical Company, Rockford, IL (1992).	
		SLOMIANY, et al., "Association of lipids with proteins and glycoproteins in human saliva," <i>J. Dent. Res.</i> 62(1):24-7 (1983).	
		SLOMIANY, et al., "Lipid composition of human parotid and submandibular saliva from caries-resistant and caries-susceptible adults," <i>Arch. Oral Biol.</i> 27(10):803-8 (1982).	
		SMITH, et al., "The plasma lipoproteins: structure and metabolism," <i>Annu. Rev. Biochem.</i> 47:751-7 (1978).	
		SNIDERMAN, et al., "Association of Coronary Atherosclerosis with Hyperapobetalipoproteinemia [Increased Protein but Normal Cholesterol Levels in Human Plasma Low Density (β) Lipoproteins], <i>Proc. Natl. Acad. Sci. USA</i> 77(1):604-608 (1980).	

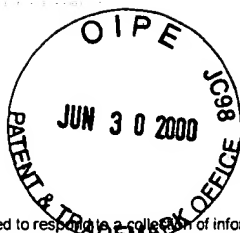
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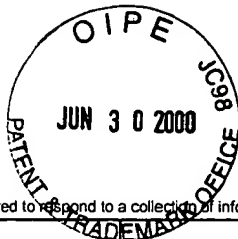
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number

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First Named Inventor

Judith Fitzpatrick

Group Art Unit

Examiner Name

Attorney Docket Number

SRX 110

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10

of

10

### OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		SOCORRO & CAMEJO, "Preparation and Properties of Soluble, Immunoreactive ApoLDL," <i>J. Lipid Res.</i> 20:631-638 (1979).	
		STEIN, et al., "Lipids, Lipoproteins, and Apolipoprotein," In <i>Tietz Textbook of Clinical Chemistry</i> , pp. 1002-1093, W.B. Saunders:Philadelphia, 1994.	
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		TOUCHSTONE, et al., "Quantitation of Cholesterol in Biological Fluids by TLC with Densitometry" <i>Adv. Thin Layer Chromatogr.</i> , Proc. Bienn. Symp. Meeting Date 1980, pp. 219-27, Wiley & Sons 2 <sup>nd</sup> ed., 1982.	
		WARNICK, et al., "Dextran Sulfate-Mg <sup>2+</sup> Precipitation Procedure for Quantitation of High-Density-Lipoprotein Cholesterol," <i>Clin. Chem.</i> 28(6):1379-1388 (1982).	
		WEEKS, et al., "Two-site immunochemiluminometric assay for human alpha 1-fetoprotein," <i>Clin. Chem.</i> 29(8):1480-3 (1983).	
		WOLLENWEBER, et al., "Comparative Serum Lipoprotein Analysis by Polyacrylamide Disc Gel and Agarose Gel Electrophoresis," <i>Clin. Chim. Acta.</i> 29:411-420 (1970).	
		WOOD, "Heterogeneous fluoroimmunoassay" In <i>Principles and Practice of Immunoassay</i> , pp. 365-392, Stockton Press:New York, 1991.	

Examiner's Signature

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